

caBIG Adverse Events Special Interest Group Teleconference  
October 1, 2004  
3:00pm – 4:00pm EDT /  
12:00pm – 1:00pm PDT

---

Agenda

- I. Review of Minutes: September 17, 2004
- II. DCP IND Studies SAE Reporting Process Diagram  
(Amy Cox – COH)
- III. CaBIG AE, CTMS-CDUS Survey Summary Review: Updated Results  
(Dr. Niland – COH)
- IV. Scope of the caBIG AE System
  - A. SAE System
  - vs.
  - B. AE Reporting System with SAE components
- V. NCI's Central IRB
  - A. Discuss the Role of NCI's Central IRB
  - B. Should an NCI Central IRB representative participate in the AE SIG teleconferences?
- VI. CaBIG CTMS Quarterly In-Person Meeting: Proposed Agenda Items:
  - A. Use Case Review
  - B. Specification for Structured Protocol
    - 1. Summary IV (2-3 hours)
    - 2. AERS (2-3 hours)
- VII. Transitioning Responsibility of Meeting Minutes:  
Designate an AE SIG Participant
- VIII. Next Teleconference: October 15, 2004